

PCT

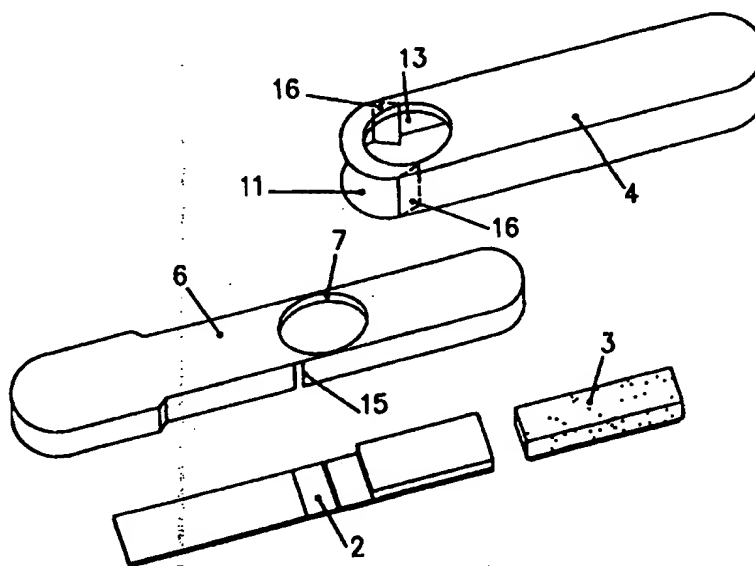
WORLD INTELLECTUAL PROPERTY ORGANIZATION
International Bureau



INTERNATIONAL APPLICATION PUBLISHED UNDER THE PATENT COOPERATION TREATY (PCT)

(51) International Patent Classification ⁶ : B01L 3/00, G01N 33/543		A1	(11) International Publication Number: WO 97/26083
			(43) International Publication Date: 24 July 1997 (24.07.97)
(21) International Application Number: PCT/EP96/05830		(81) Designated States: AL, AM, AT, AU, AZ, BA, BB, BG, BI, BY, CA, CH, CN, CU, CZ, DE, DK, EE, ES, FI, GB, GI, HU, IL, IS, JP, KE, KG, KP, KR, KZ, LC, LK, LR, LT, LU, LV, MD, MG, MK, MN, MW, MX, NO, NZ, PT, RO, RU, SD, SE, SG, SI, SK, TJ, TM, TR, TT, UG, US, UZ, VN, ARIPO patent (KE, LS, MW, SD, S: UG), Eurasian patent (AM, AZ, BY, KG, KZ, MD, RU, T TM), European patent (AT, BE, CH, DE, DK, ES, FI, F GB, GR, IE, IT, LU, MC, NL, PT, SE), OAPI patent (B: BJ, CF, CG, CI, CM, GA, GN, ML, MR, NE, SN, TD, TG	
(22) International Filing Date: 23 December 1996 (23.12.96)			
(30) Priority Data: MI96A000069 17 January 1996 (17.01.96) IT			
(71) Applicant (for all designated States except US): BOEHRINGER MANNHEIM ITALIA S.P.A. [IT/IT]; Via S. Uguzzone, 5, I-20126 Milano (IT).			
(72) Inventors; and (75) Inventors/Applicants (for US only): QUAGLIARELLA, Giovanna [IT/IT]; Viale della Libertà, Km. 0,750, I-20052 Monza (IT). PIRO, Paola [IT/IT]; Viale della Libertà, Km. 0,750, I-20052 Monza (IT). FIFIELD, Bruce [US/IT]; Viale della Libertà, Km. 0,750, I-20052 Monza (IT). SMEENK, Nico [NL/IT]; Viale della Libertà, Km. 0,750, I-20052 Monza (IT). CANTONE, Roberta [IT/IT]; Viale della Libertà, Km. 0,750, I-20052 Monza (IT). DELLA CROCE, Paolo [IT/IT]; Viale della Libertà, Km. 0,750, I-20052 Monza (IT).			
(74) Agent: SPADARO, Marco; Studio Consulenza Brevettuale, Via Rossini, 8, I-20122 Milano (IT).		Published With international search report.	

(54) Title: DEVICE FOR THE CARRYING OUT OF RAPID DIAGNOSTIC TESTS ON SAMPLES OF LIQUIDS



(57) Abstract

Device for the carrying out of rapid diagnostic tests on samples of liquids, including a casing (1) enclosing a pad (3) for collect the liquid sample at one end and a porous strip; analysis reagent (2), visible through a window (7) in the casing (1), as well as an exter protective shell (4), also provided with a window (13) called shell (4) being movable on the envelope (1) between at least two positio a withdrawn position in which it leaves the porous strip (3) exposed for the collection of liquid samples and covers the window (7) of casing (1), and an advanced position in which it covers the porous strip (3) and places its window (13) in register with the window (7) the casing (1), for reading the result of the test.

BEST AVAILABLE COPY

FOR THE PURPOSES OF INFORMATION ONLY

Codes used to identify States party to the PCT on the front pages of pamphlets publishing international applications under the PCT.

AM	Armenia	GB	United Kingdom	MW	Malawi
AT	Austria	GE	Georgia	MX	Mexico
AU	Australia	GN	Guinea	NE	Niger
BB	Barbados	GR	Greece	NL	Netherlands
BE	Belgium	HU	Hungary	NO	Norway
BF	Burkina Faso	IE	Ireland	NZ	New Zealand
BG	Bulgaria	IT	Italy	PL	Poland
BJ	Benin	JP	Japan	PT	Portugal
BR	Brazil	KE	Kenya	RO	Romania
BY	Belarus	KG	Kyrgyzstan	RU	Russian Federation
CA	Canada	KP	Democratic People's Republic of Korea	SD	Sudan
CF	Central African Republic	KR	Republic of Korea	SE	Sweden
CG	Congo	KZ	Kazakhstan	SG	Singapore
CH	Switzerland	LI	Liechtenstein	SI	Slovenia
CI	Côte d'Ivoire	LK	Sri Lanka	SK	Slovakia
CM	Cameroon	LR	Liberia	SN	Senegal
CN	China	LT	Lithuania	SZ	Swaziland
CS	Czechoslovakia	LU	Luxembourg	TD	Chad
CZ	Czech Republic	LV	Latvia	TG	Togo
DE	Germany	MC	Monaco	TJ	Tajikistan
DK	Denmark	MD	Republic of Moldova	TT	Trinidad and Tobago
EE	Estonia	MG	Madagascar	UA	Ukraine
ES	Spain	ML	Mali	UG	Uganda
FI	Finland	MN	Mongolia	US	United States of America
FR	France	MR	Mauritania	UZ	Uzbekistan
GA	Gabon			VN	Viet Nam

DEVICE FOR THE CARRYING OUT OF RAPID DIAGNOSTIC TESTS ON
SAMPLES OF LIQUIDS

The subject of this invention is a device for the carrying out of rapid diagnostic tests on samples of liquids and in particular tests on urine samples on immunochromatographic membranes, such as HCG Human
5 Chorionic Gonadotropin (pregnancy), FSH Follitropin (identification of the follicular phase), LH Human Luteotropin (identification of the fertile period) etc.

Various devices which allow the carrying out of the above mentioned rapid tests are known, conceived for use
10 by unskilled persons.

Such devices essentially include a porous analysis strip containing a predetermined quantity of reagent which changes colour upon contact with the liquid to be analysed in giving an almost immediate indication of the
15 test result.

The simplest devices consist of the porous analysis strip only, with an absorbent end, which is soaked, for example by immersion in the liquid to be analysed. Such devices, even though simple and of low cost, turn out to
20 be unsuitable from a hygienic point of view as they require direct contact with the user's hands, even after immersion in the sample and necessarily require that the sample be collected in a suitable container.

Therefore devices have been thought of which are
25 simpler to use and safer from a hygiene point of view and which have an external protective casing for the porous analysis strip and which allow the test to be carried out by simple exposure to the sample, without

this having to be collected.

One such device is described, for example, in EP-A-653 639 and comprises a prolonged casing, made in two halves, between which the porous analysis strip is included together with a small absorbent pad, positioned so as to protrude from one end of the casing. There is a window on one of the two halves of the casing, through which the result of the test can be read. This window is situated near to the opposite end of the casing from the one from which the absorbent pad protrudes. The device is completed by at least an external protective hood which is applied to the casing in such a way as to cover the window during the taking of the liquid sample to prevent the liquid from entering through the window and thus prejudicing the test result. After the pad has been soaked in liquid, the protective hood is removed from the casing and placed on its other end so as to cover the pad.

This device is of rather complicated construction, and, being made in a variety of separate pieces, therefore costly. It also requires particular care on the part of the user who must necessarily use both hands to place the hood at one end or the other at different points in the test and this can include hygiene problems with the possibility of contact of the sample with the hands not being absolutely excluded.

JP-0712467, JP-0712468, JP-07120465 and JP-07120466 describe devices of this same type and of different conformations but all lacking any protection of the reading window against contamination by the liquid sample.

An object of the invention is to supply a device for rapid diagnostic tests on samples of liquids which can be used simply and safely by unskilled persons and which assures the maintaining of conditions of hygiene during use.

Another object of the invention is to supply a device which is relatively simple and of low cost.

A further object of the invention is to supply such a device which can be manipulated with one hand only.

These objects are attained in the device according to the invention which presents the characteristics listed in the independent claims annexe.

Preferred versions of the device according to the invention are coupled with dependent claims.

Substantially, the device according to a version of the invention has a casing containing the porous analysis strip and a liquid absorbent pad which protrudes for a certain distance from its end. This casing has at least one window and is housed in an axially sliding external shell which is also provided with a movable window to register with the window in the casing.

In particular, the external shell is movable from a backward position in which it leaves the pad uncovered and closes the window in the casing below, to allow the sampling of the liquid without risk of contamination of the window, and a forward position in which it covers the protruding pad and superimposes its window on the one in the casing underneath to allow the result of the test to be seen.

The user need therefore only slide the external

shell after sampling the liquid, to cover the pad and look at the test result; an extremely simple operation which can be carried out with one hand and which allows operation in conditions of maximum hygiene.

5 According to a variant version, the porous analysis strip and the absorbent pad are carried by a sliding cursor inside the containing casing and having a control protruding from a longitudinal slot cut in the casing so that it can be moved from a position of liquid sampling,
10 in which the pad protrudes from the casing, to a position of reading in which the porous analysis strip is in correspondence with the window in the casing. This version further simplifies use of the device with one hand only.

15 Further features of the invention will be clarified by the detailed description which follows and which is in a purely exemplary form and therefore not limited to the versions shown on the attached drawings, of which:

20 Figure 1 is a plan view of a form of the device according to the invention, with the pad exposed;

 Figure 2 is a side view of the device of Figure 1;

 Figure 3 is a plan view similar to the one in Figure 1, with the pad covered and the window in
25 register;

 Figure 4 is an end view taken from the right-hand side of Figure 1;

 Figure 5 is an exploded view of the device.

30 Figure 6 is an axonometric view of the assembled device, without its external protective shell;

 Figure 7 is a plan view of a second form of the device

5

according to the invention, with the pad exposed;

Figure 8 is a side view of the device of Figure 7;

Figure 9 is a plan view similar to that of Figure 7,
5 with the pad covered and the analysis strip in the reading position, registered with the casing window;

Figure 10 is an exploded view of the device in Figure 7

10 With reference to Figures 1 to 6, the device according to the invention includes a casing or body 1, enclosing a porous analysis strip 2 and an absorbent pad 3, which protrudes from one end, and a protective external shell 4.

15 The casing 1 has a long form and consists of two halves, one lower 5 and one upper 6, substantially equal and fitting together so as to accommodate inside them, the porous reagent strip 2, visible through an oval window 7 situated in the upper half 6, and to press on and off the pad 3, which is also of elongated shape and
20 which is in contact with the strip 2, of which it constitutes a prolongation. To allow the exit of the pad 3, the walls of the two halves of the casing 1 have a hollow space 8, at one end.

25 The casing or body 1 on the side opposite to the pad 3 has a slight widening 9, creating a couple of lateral spaces 10.

30 The external shell 4, has an opening 11 at one end to insert the elongated casing 1 and another opening 12 at the other end (figure 4) for the passage of the pad 3.

An oval window 13, is placed on the upper side of

the shell 4, with dimensions not less than those of the window 7 on the casing 1 and which can be brought into register with the latter to allow the reading of the porous strip 2.

5 To allow the correct positioning of window 13 on window 7 and to prevent the slipping off of the protective shell 4 from the casing 1, means of reciprocal attachment can be provided, achieved, for example by a couple of lateral notches 15 cut in the
10 casing 1 and by corresponding flexible tongues 16 on the internal walls of the shell 4, preferably in correspondence with the opening 11. The flexible tongues 16 are oriented in such a way as when the casing 1 is inserted in the shell 4, they bend and pass over the
15 notches 15, whereas when moved in the opposite direction, they engage with the notches 15.

Naturally, there are other methods of fastening between the casing 1 and the shell 4 which could be used.

20 With reference now to Figures 1 to 3 in particular, the functioning during use of the device according to the invention is illustrated.

In the liquid sample collection phase, particularly of urine, the device according to the invention is in
25 the arrangement shown in Figure 1, with the outside shell 4 withdrawn on the casing or body 1, so as to abut against the couple of lateral spaces 10 on the casing 1. In this condition, the pad 3, protrudes from the device and can so be used to collect the sample, either by
30 immersing it into a collection container or by placing it directly in the patient's urine flow.

7

In any case, the user's fingers which hold the device at the opposite end from the pad 3 are well distant from the collection area and are therefore well protected.

5 In the same way, the window 7 in the casing 1, is protected by the external shell 4, in eliminating all risk that urine spray could directly reach the porous strip 2 below.

10 Once the sample collection is completed, the user slides the outside shell 4 on the casing 1, until the flexible tongues 16 engage with the corresponding notches 15.

15 In this condition, shown in figure 3, the pad 3 is covered by the shell 4, thus avoiding contact with the sample and possible drips outside and at the same time, the window 13 of the shell 4 goes into register with the window 7 of the casing 1 underneath, in making the porous analysis strip 2 visible and upon which the test result appears, shown in schematic form from line 20 in
20 Figures 3 and 6.

In the case that the test result is not directly visible on the porous strip 2, but requires special reading as occurs in some types of analysis, the device according to the invention, in the condition shown in
25 Figure 3, is taken to the reading machine, to be considered as known.

Both the casing 1 and the shell 4 are conveniently made in plastic material, polystyrene for example, and the two halves 5 and 6 of the casing 1 can be joined
30 together in any way, even by welding, ultrasonic welding for example.

It can be furthermore foreseen that the pad 3 is mainly or completely housed in the casing 1 and is accessible to be soaked in liquid through holes made in the casing.

5 From what has been written above, the advantages of the device according to the invention appear evident and it can also be operated with one hand. To facilitate this, grips can be provided on the casing 1 and/or on the outside shell 4. For example a finger hold can be
10 provided on the casing 1 and/or a couple of lateral incisions with curved profile on the outside shell 4 or on the casing 1.

The outside shell 4 can be longer than shown in the attached Figures, so as to allow an intermediate
15 position between the two shown in Figures 1 and 3, position in which the shell 4 covers both the pad 3 and the window 7 of the casing 1.

The version of Figures 7 to 10 is now described, in using the same reference numbers as in the previous
20 version to distinguish between equal or similar parts.

Substantially, in this version, the porous analysis strip 2 and the absorbent pad 3 are supported by a cursor 30, moveable axially inside the casing 1, from a position in which the pad 3 protrudes from the casing to
25 allow the collection of the sample liquid (Fig. 7), to a position in which the pad 3 is covered by the casing 1 and the analysis strip 2 is in correspondence with the window 7 in the casing to allow reading. Movement of the cursor 30 is by means of a control 31, protruding
30 through a longitudinal slot 32 in the casing 1.

During the collection of sample liquids (Fig. 7),

an impermeable film 33 applied to the cursor 30 (Fig. 10), provides tightness beneath the window 7, to prevent any liquid infiltrations.

CLAIMS

1. Device for the carrying out of rapid diagnostic tests on liquid samples, comprising a casing (1) enclosing a pad (3) for the collection of liquid samples at one end and a porous analysis strip (2), on which the test result can be read through at least one window (7) in the said casing (1), as well as an external shell (4) also with at least one opening (13) and movable on the casing (1) between at least two positions: a withdrawn position in which it leaves the said pad 3 exposed and covers the said window (7) in the casing (1), and an extended position in which it covers the said pad (3), with its window (13) in register with the said window (7) of the casing (1).
2. Device according to claim 1, characterized by the fact that means are foreseen for the correct positioning of the said shell (4) with respect to the said casing (1) in at least two positions, withdrawn and extended.
3. Device according to claim 2, characterized by the fact that the said means for the correct positioning of the shell (4) in the withdrawn position comprises a couple of lateral incisions (10) made on the casing (1) against which is placed an open end (11) of the shell (4) through which the casing (1) is inserted.
4. Device according to the invention, characterized by the fact that the said means of positioning the shell (4) in the said extended position includes a couple of lateral notches (15) in the casing (1) which engage flexible tongues (16) in the shell (4), or vice versa.
5. Device according to any of the previous claims,

11

characterized by the fact that the said porous strip (2) and said pad (3) are disposed in alignment between themselves and are in contact with each other.

6. Device according to any of the previous claims, characterized by the fact that the said pad (3) protrudes at least partially from a corresponding end of the casing (1) and can be inserted into a terminal opening (12) of the shell (4) opposed to the said opening (11).

7. Device according to any of the previous claims, characterized by the fact that the said casing (1) is made in two halves (5) and (6) which can be joined together.

8. Method of using the device for rapid diagnostic tests on samples of liquids according to any of the previous claims, in which the said device is held by the user with the shell in the said withdrawn position, so that the said pad (3) can collect the urine sample, after which the said shell (4) is moved to the said extended position to allow the reading of the test result through the superimposed windows (13), (7).

9. Method according to claim 8, in which the shell (4) before being brought into the withdrawn position for the collection of sample liquid, is in an intermediate position in which it covers both the said pad (3) and the said window (7) of the casing (1).

10. Device for carrying out rapid diagnostic tests on samples of liquids, comprising a casing (1) enclosing a pad (3) for the collection of the liquid sample at one end and a porous strip, analysis reagent (2) on which can be read the test result through at least one window

12

(7) in the said casing (1), characterized by the fact that the said sample (3) and said analysis strip (2) are carried by a cursor (30) sliding inside the casing (1) between a position in which the pad (3) protrudes from the casing (1) and the said porous analysis strip (2) is placed in correspondence with the said window (7) in the casing (1) to allow reading.

11. Device according to claim 10, characterized by the fact that the said cursor (30) has a control (31) protruding through a longitudinal slot (32) in the casing (1).

12. Device according to claims 10 and 11, characterized by the fact that an impermeable film (33) is foreseen on the said cursor (30) and which provides tightness beneath the said window (7) in the casing (1) when the said pad (3) is protruding from the casing to collect the liquid sample.

Fig. 1

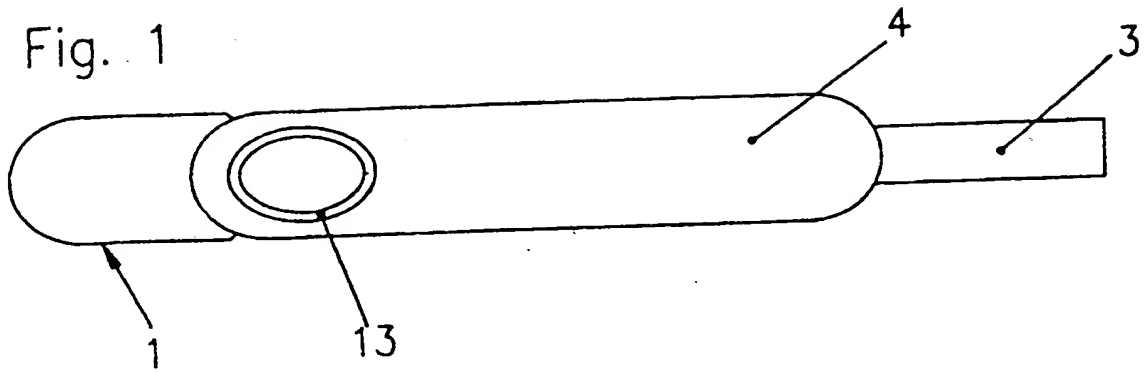


Fig. 2

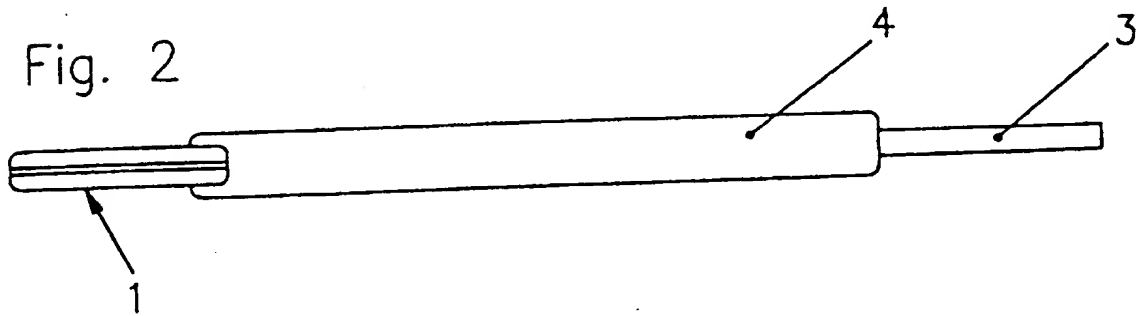


Fig. 3

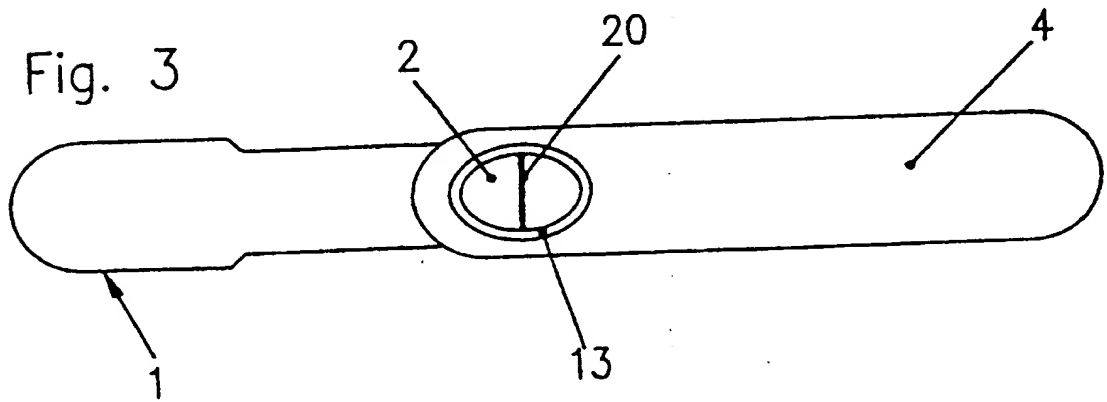
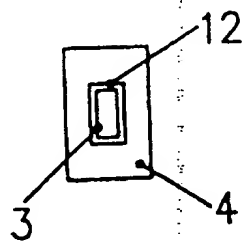


Fig. 4



2/4

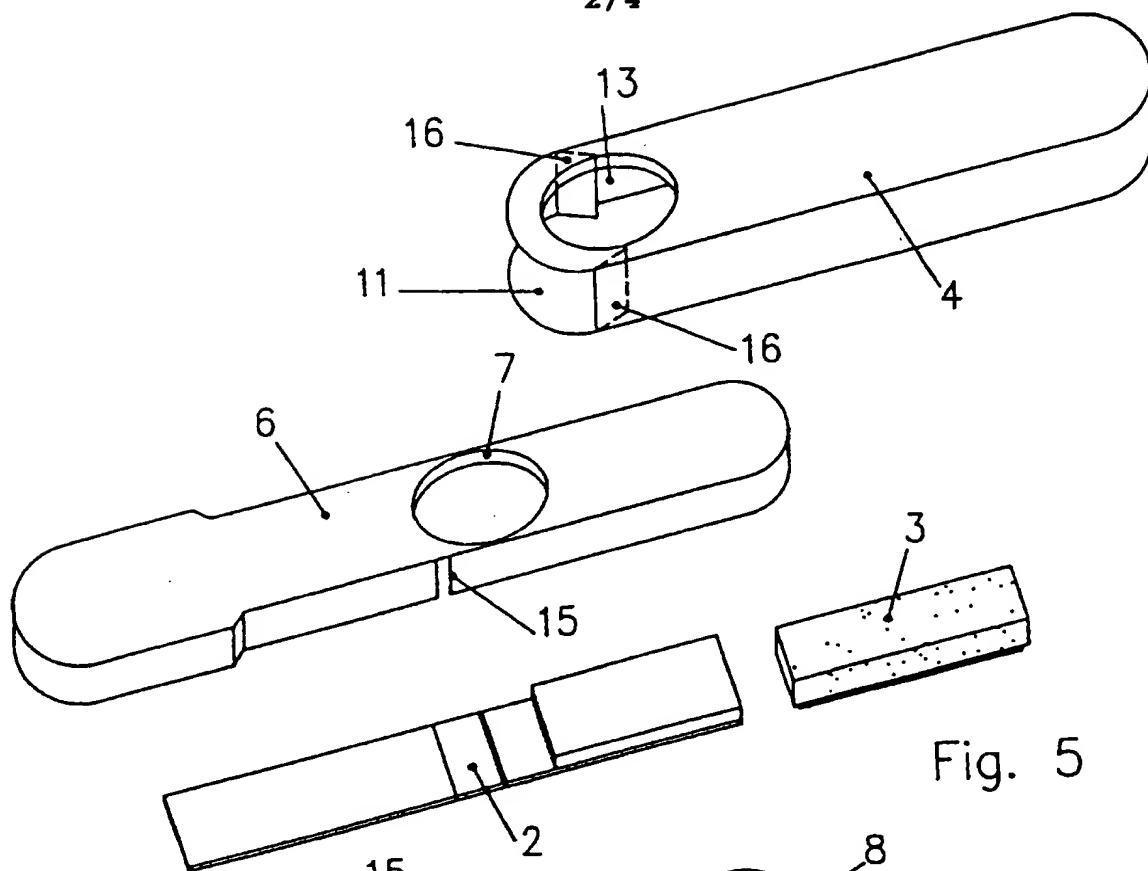


Fig. 5

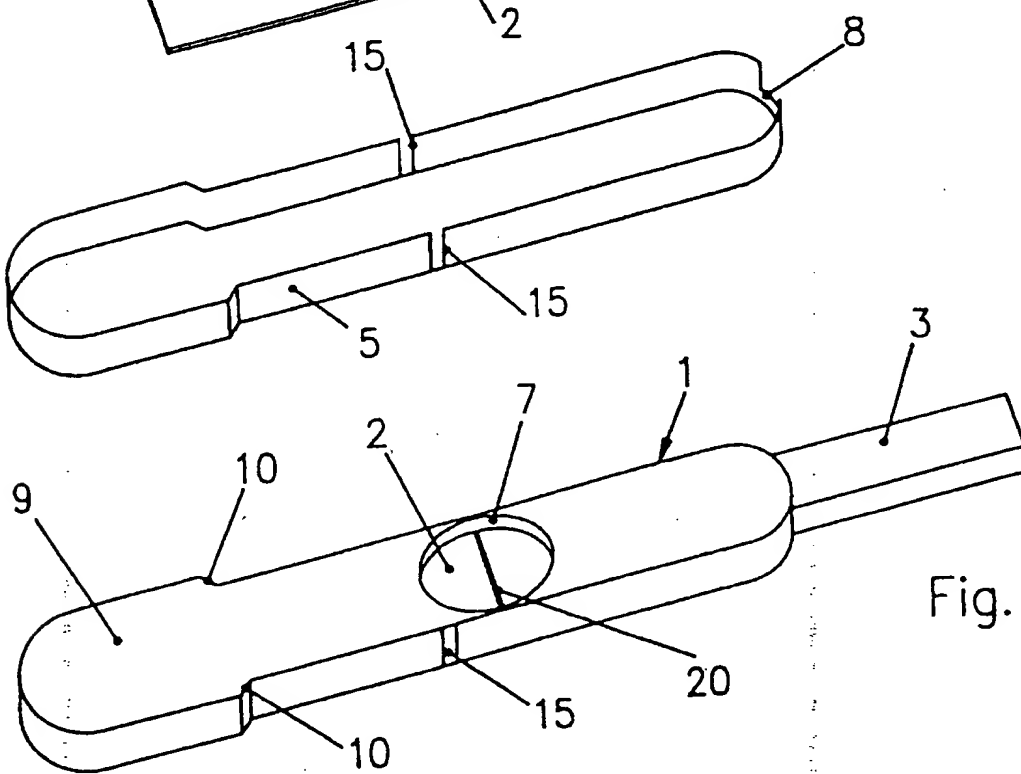
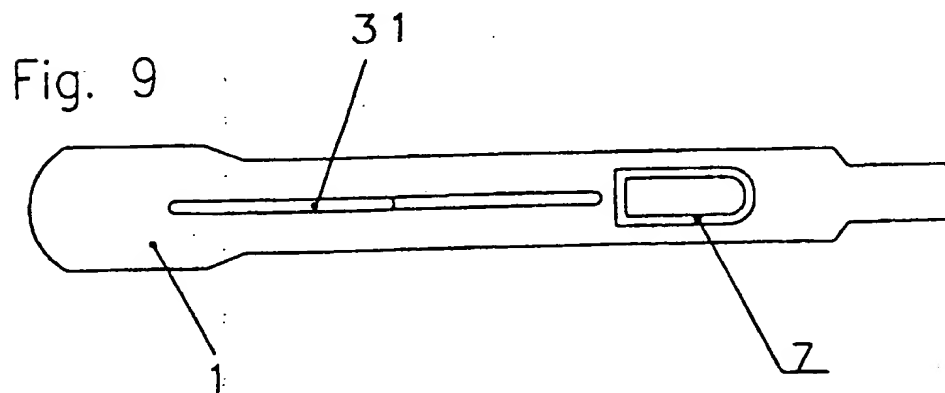
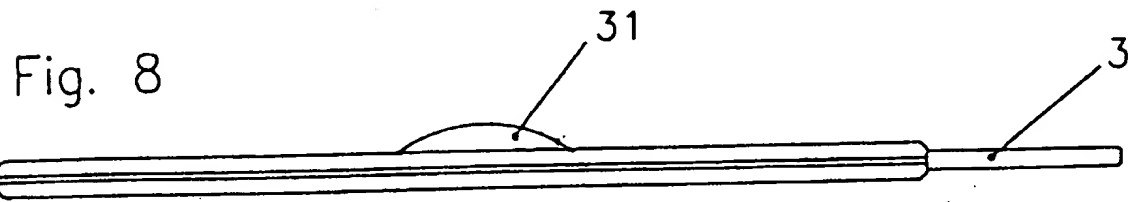
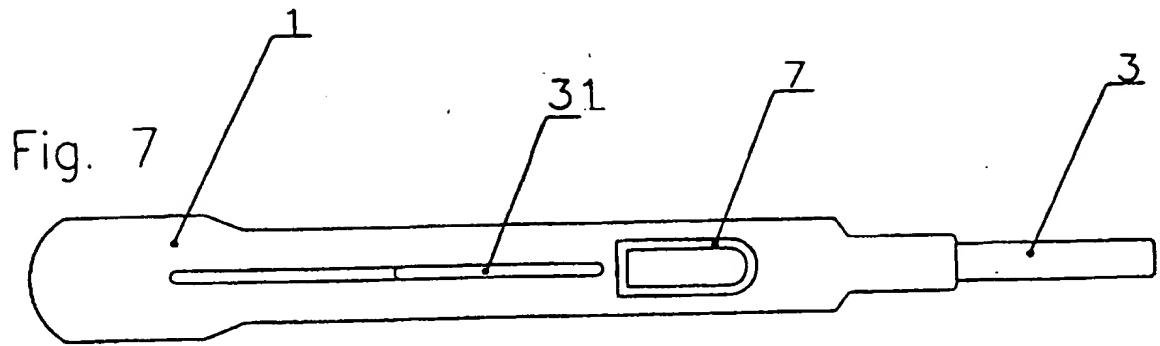
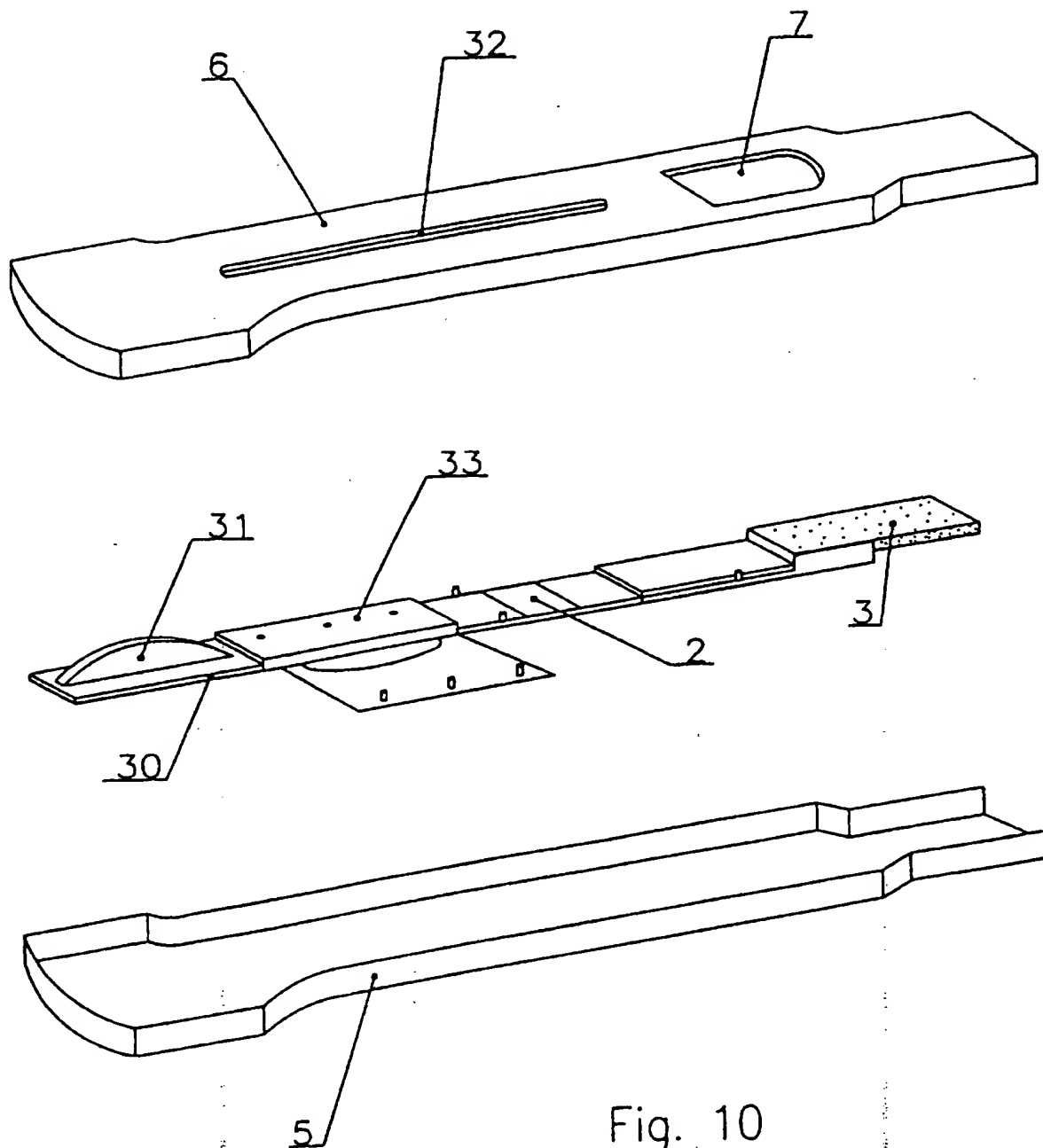


Fig. 6



4/4



INTERNATIONAL SEARCH REPORT

Int. nal Application No
PCT/EP 96/05830

A. CLASSIFICATION OF SUBJECT MATTER
IPC 6 B01L3/00 G01N33/543

According to International Patent Classification (IPC) or to both national classification and IPC

B. FIELDS SEARCHED

Minimum documentation searched (classification system followed by classification symbols)
IPC 6 B01L G01N

Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched

Electronic data base consulted during the international search (name of data base and, where practical, search terms used)

C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category *	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
X	WO 95 08761 A (POLYFILTRONICS INC) 30 March 1995 see page 4, line 28 - page 7, line 6 see page 9, line 5 - line 12; figures 1-5,9	10,11
A	US 5 238 652 A (SUN MING ET AL) 24 August 1993 see column 6, line 62 - column 7, line 48	1,2,8
A	EP 0 653 639 A (UNIPATH LTD) 17 May 1995 cited in the application see column 5, line 4 - column 6, line 55	1,8
	-/--	

☒ Further documents are listed in the continuation of box C.

☒ Patent family members are listed in annex.

* Special categories of cited documents:

- *A* document defining the general state of the art which is not considered to be of particular relevance
- *E* earlier document but published on or after the international filing date
- *L* document which may throw doubts on priority claim(s) or which is cited to establish the publication date of another citation or other special reason (as specified)
- *O* document referring to an oral disclosure, use, exhibition or other means
- *P* document published prior to the international filing date but later than the priority date claimed

- *T* later document published after the international filing date or priority date and not in conflict with the application but cited to understand the principle or theory underlying the invention
- *X* document of particular relevance; the claimed invention cannot be considered novel or cannot be considered to involve an inventive step when the document is taken alone
- *Y* document of particular relevance; the claimed invention cannot be considered to involve an inventive step when the document is combined with one or more other such documents, such combination being obvious to a person skilled in the art
- *A* document member of the same patent family

Date of the actual completion of the international search

11 April 1997

Date of mailing of the international search report

23.04.97

Name and mailing address of the ISA

European Patent Office, P.B. 5818 Patentlaan 2
NL - 2280 HV Rijswijk
Tel. (+31-70) 340-2040, Tx. 31 651 epo nl,
Fax (+31-70) 340-3016

Authorized officer

Bindon, C

INTERNATIONAL SEARCH REPORT

International Application No
PCT/EP 96/05830

C.(Continuation) DOCUMENTS CONSIDERED TO BE RELEVANT

Category *	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
A	PATENT ABSTRACTS OF JAPAN vol. 95, no. 005 & JP 07 120467 A (DAINIPPON PRINTING CO LTD), 12 May 1995, cited in the application see abstract ---	1,8
A	PATENT ABSTRACTS OF JAPAN vol. 95, no. 001 & JP 07 027761 A (SANKYO CO LTD; OTHERS: 01), 31 January 1995, see abstract -----	1,8

INTERNATIONAL SEARCH REPORT

Information on patent family members

Int: nal Application No

PCT/EP 96/05830

Patent document cited in search report	Publication date	Patent family member(s)	Publication date
WO 9508761 A	30-03-95	NONE	
US 5238652 A	24-08-93	AU 8054291 A	07-01-92
		CA 2085731 A	21-12-91
		EP 0535133 A	07-04-93
		WO 9119980 A	26-12-91
EP 0653639 A	17-05-95	AU 7994194 A	29-05-95
		BR 9408040 A	24-12-96
		CA 2173966 A	18-05-95
		CN 1134751 A	30-10-96
		CZ 9601319 A	11-09-96
		DE 9418147 U	16-02-95
		WO 9513541 A	18-05-95
		ES 1030750 U	01-10-95
		FR 2712392 A	19-05-95
		IT T0940228 U	12-05-95
		NZ 274853 A	28-10-96
		PL 314302 A	02-09-96
		US 5504013 A	02-04-96
		ZA 9408783 A	07-05-96

THIS PAGE BLANK (USPTO)